CURRENT CHALLENGES OF EUROPEAN MARKET SURVEILLANCE REGARDING PRODUCTS SOLD ONLINE*

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A number of changes and challenges impacted the global economy over the last decades. The trade of goods used to be carried out through relatively controllable and predictable routes, so the market surveillance measures, institutions and powers that could form the foundations of an efficient system are now not necessarily capable of providing the same high level of consumer safety. Rules created in the context of identifiable manufacturers, distributors established in the internal market, physical shops and markets are no longer suitable for facing the market surveillance challenges of the online market. The present study analyses the changes and the latest achievements of the legal framework, that can be considered as milestones of market surveillance and product safety regulations.

Introduction

Many things have changed in the global economy over the last 40 years. The trade of goods used to be carried out through relatively controllable and predictable routes, so the market surveillance measures, institutions and powers that could form the foundations of an efficient system are now not necessarily capable of providing the same high level of consumer safety. Rules created in the context of identifiable manufacturers, distributors established in the internal market, physical shops and markets are no longer suitable for facing the market surveillance challenges of the online market.

The large increase in the movement of goods, the volume of products flowing into the European Union through personal orders can no longer be controlled and tracked by traditional methods (Jadhav & Khanna 2016, 1–15). Behind the displayed offers of an online store a stock of a trader cannot necessarily be found, especially one's that is established in the European Union (Massad & Berardelli 2016, 26–37). In addition, warehouses are being set up within the borders of the EU for goods that had entered the European Union and later were withdrawn, that, until now, have fallen outside the control of market surveillance authorities.

At the same time, consumers expect the same level of protection for products manufactured inside and outside the EU. In our globalized world, it remains a challenge to ensure that the imported products comply with EU standards but also do not gain an unfair competitive advantage by violating EU rules. Imported products should, in principle, be inspected when they enter the single market. However, the volume of imported products makes it impossible to control all shipments. In 2015, more than 30%

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of products entering EU markets came from imports. Their estimated worth was almost € 750 billion (EC, 2017c).

In my study, I am looking for the answer whether a high level of protection of the health and physical integrity of consumers can be guaranteed in the internal market in the changed circumstances. Therefore, I review the changes and the latest achievements of the legal framework, that can be considered as milestones of market surveillance and product safety regulations.

1. The inceptions of European product safety regulation

The mid-1980s saw an in-depth legislative review process, marked as a 'New Approach', that established rules for the distribution of products within the EU. The aim was for EU legislation to focus only on public interest requirements for product conformity, while leaving the definition of detailed technical requirements to standards. The New Approach contributed to the development of the European standardization process and the EU harmonization acquis. As part of this process, more than 30 directives were implemented in the Member States' legal systems between 1987 and 2000.

In the early 1990s, with the adoption of the Maastricht Treaty on European Union and the establishment of Economic and Monetary Union, the role of harmonization in the EU's single market was strengthened. On the one hand, the EU has developed a policy aiming to strengthen European standardization, that covered all the technical requirements of product specifications, while giving manufacturers more flexibility to demonstrate compliance. The European standardization process has been consolidated by a number of legislative documents, including Council Directive 93/68/EEC, that amended certain sectoral harmonized legislation by introducing the CE marking. On the other hand, with the Union (Community) Customs Code, the EU supported customs authorities and traders in ensuring the correct application of customs legislation and the right of traders to fair treatment.

With Council Regulation (EEC) No. 339/93. (Regulation (EC) No 765/2008) the EU institutions, for the first time, focused on the system of market surveillance institutions and common rules for the control of products from outside the EU in order to ensure compliance with product safety provisions in the internal market.

In 2001, as the next step of harmonization, the EU legislator improved the level of consumer safety by adopting Directive 2001/95/EC the so-called General Product Safety Directive (GPSD). Taking into account the principle of lex specialis, the general safety requirements of the GPSD did not apply to medical devices, cosmetics and to product categories for which the EU has specific legislation.

The results of the public consultation launched in 2002 suggested the need for a reform process that focuses on the lack of confidence in eligible institutions and the whole notification process, the weaknesses in market surveillance and the need for further enforcement measures, the inconsistencies between different directives and the misunderstandings of the role and value of the CE marking.

In the following years, a lively dialogue between the EU institutions, experts from EU Member States and stakeholders led to a review of New Approach initiatives and

the adoption of a new legislative framework in 2008. As a result, following an impact assessment, the EU institutions adopted Regulation (EC) No 765/2008 that set out the requirements for accreditation and market surveillance relating to the marketing of products, and repealed Regulation (EEC) No 339/93.

The rules laid down in Directive 2001/95/ EC shall be applied to products regardless of how they are sold (including a product provided in connection with a service), but their scope does not extend to services. However, the definition of a product under the Directive is extremely broad, so that it covers all products that are intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.

As a general rule, the obligation to produce safe products (and allow to be distributed) is imposed on manufacturers. It should also be noted that, under the Directive, distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements. In this context, EU and national rules on market surveillance are intended to ensure the withdrawal of those products, that may endanger the health or safety of users when used as intended or under reasonably foreseeable conditions and when properly installed and maintained, to prohibit or restrict their distribution, and to ensure adequate publicity and information in this regard. It can be stated that Regulation (EC) No 765/2008 has brought a fundamental change of approach, as it has taken a broader view of market surveillance than the previous regulations and included into its scope the control of compliance with all marketing requirements.

2. Challenges of the market surveillance system in the changed environment

Weaknesses in market surveillance have already been pointed out by many actors in Europe, including consumer organizations, industries, the European Parliament and the European Commission, the reasons for that can be traced back mainly to the following factors and changes. Supply chains have become very complex and manufacturers are often located outside the EU, while in many cases the importer – from a traditional context – cannot be identified. Consumers regularly buy products from third countries via the internet, so the products reach the consumers directly, thus evading the product conformity and import inspections of the customs authorities in most cases. It should be noted here, however, that the power (authority) and obligation to control exist in the same way if the product is delivered to the border control in the form of private consignment or a non-concentrated consignment, but random checks obviously cannot be as effective.

One of the structural weaknesses of the single market for goods is related to the enforcement of harmonized EU product safety rules. Even though there are extensive safety rules, there are still too many illegal and unsafe products on the market. These products pose a high risk to consumers. Another vulnerability factor of the system is

that products that are not covered or only partially covered by harmonized EU product safety rules, such as furniture or certain construction industry products, are not subject to specific rules. These products can be considered safe in one Member State and are in conformity with the public interest, while in another Member State they could have difficulties in accessing the market. EU legislation has established risk-oriented and general product safety rules. Too many new types of products and safety risks are excluded from the scope of the GPSD (despite that its scope is designated in general), while specific rules cannot, by their nature, cover all risks (see the rules on the chemical composition of consumer products, rules on chemicals).

Although there is an institutional, legal framework for cooperation between Member States, it is nevertheless difficult to detect and recall unsafe products from the market. Although the RAPEX system is an effective platform for rapid communication between market surveillance authorities, the institutional acquisition of other information would be necessary to set up a harmonized European product safety risk map. The NEISS database in the USA can serve as a model for this (NEISS 2000, 7.). NEISS is a database that provides statistical estimates of injuries related to consumer products from a probability sample of approximately 100 hospital emergency care departments (Marker & Lo 1996). In addition, it collects additional data both at supervisory and at investigatory platforms. NEISS collects its data through the continuous routine monitoring of emergency the departments, the surveillance of the special emergency departments, the telephone interviews with the injured, and ton-site inspections of injured and witnesses (NEISS 2000, 7.). The data collected identifies injuries related to specific consumer products and allows further analysis of the product.

Recognizing the weaknesses of the European market surveillance system, as a possible solution the European Parliament and the Council of the European Union adopted on 20 June 2019 the Regulation (EU) 2019/1020 on market surveillance and product conformity as part of a program (so-called 'Goods Package') providing measures that can offer adequate solution to some of the problems detailed above (Regulation (EU) 2019/1020). The package contains two ambitious legislative proposals (EC, 2017a). The first proposal aims to improve the compliance with and the enforcement of EU product rules. The second proposal aims to review and facilitate the use of mutual recognition in the single market (EC, 2017b).

3. A possible way for a solution: new market surveillance regulation

The 'Goods Package' is a wider scope of legislative proposal aimed at ensuring that products entering the European Union (EU) single market are safe and in conformity with the public interests protected by EU legislation, such as the protection of health and safety in general, the occupational health and safety, the protection of consumers and the public safety. As a result, the provisions of the Market Surveillance Regulation apply to products that are covered by 90 named EU regulations and directives in sectors such as medical devices, cosmetics, vehicles, toy safety, chemicals, packaging and waste.

The Market Surveillance Regulation aims to meet the challenges posed by global markets and complex supply chains, as well as the increase in online sales to end-users

in the EU. In order to strengthen the current market surveillance system, the challenges posed by the EU, the cross-border e-commerce and online commerce should be addressed, joint activities of market surveillance authorities, other relevant authorities and organizations representing economic operators or consumers of several Member States should be encouraged, also, the digital exchange of information between the authorities, trade unions and the European Commission should be improved. In addition, the regulation aims to establish an EU product conformity network as a platform for coordination and cooperation between Member States' authorities and the Commission; also, it intends to work closely with customs authorities to control products from outside the EU more effectively.

3.1. The focus on the entire supply chain

One of the most important results of the Market Surveillance Regulation is that it pays special attention to economic operators. With this, it is aimed to provide an adequate response to a phenomenon that is becoming quite worrying today, namely that the supply chain, especially for products sold online, has become impenetrable, contingent or even unidentifiable. The effectiveness of the market surveillance system is also significantly hampered by the fact that, as a result of direct sales to consumers, importers can no longer be identified in the classical sense and the consumer cannot be expected to comply with European legislation.

Under the Market Surveillance Regulation, the products covered can only be placed on the market if the underlying economic operator established in the EU can be identified. The economic operator shall be responsible for ensuring that the conformity documentation is available, shall cooperate with the market surveillance authorities and inform the authorities if there are grounds for believing that a product presents a risk. For the purposes of the Market Surveillance Regulation, an economic operator shall be a manufacturer established in the EU, an importer if the manufacturer is not established in the EU, an authorized representative of the manufacturer with a written mandate to act on behalf of the manufacturer; or in all other cases, Fulfillment service providers (FSPs) established in the EU, if there is no other economic operator established in the EU. The purpose of the Regulation is, inter alia, to apply the EU law to all economic operators involved in the supply and distribution chain in accordance with the extent of their intervention or participation.

3.2. The nature of liability extended to fulfilment service providers

Traditionally, economic operators, such as the manufacturer of the goods, the importer (if the manufacturer is not established in the EU) or the authorized representative, are responsible for placing the products on the EU market. However, there is an increasing number of economic operators who sell directly to consumers through e-commerce. Fulfilment service providers that perform the same functions as importers, but which do not always meet the traditional definition of importers in EU law, are now covered by the legislation. With the development of direct sales and online commerce, consumers

may become 'importers' within the EU, but at the same time these consumers are clearly unable to ensure that products entering the EU comply with EU legislation. This is precisely why the legislator has extended the definition of economic operator in the Market Surveillance Regulation to fulfilment service providers who provide at least two of the warehousing, packaging, addressing and dispatch services without owning the products in question. Exceptions to this are postal services; parcel delivery services; and any other postal or freight services.

The Market Surveillance Regulation considers that a product offered for sale online or through other means of distance sales, should be considered to have been made available on the market if the offer for sale is targeted at end users in the Union, thus, if the relevant economic operator directs, by any means, its activities to a Member State. For the case-by-case analyses, relevant factors, such as the geographical areas to which dispatch is possible, the languages available, used for the offer or for ordering, or means of payment, need to be taken into consideration. In the case of online sales, the mere fact that the economic operators' or the intermediaries' website is accessible in the Member State in which the end user is established or domiciled is insufficient.

3.3. Stricter market surveillance powers

The Market Surveillance Regulation confers enhanced powers on national market surveillance authorities to ensure compliance with EU law for products purchased both in the online and offline market. Access to information is essential for the exercise of effective market surveillance powers. Under the Regulation, economic operators are obliged to provide relevant data or information to market surveillance authorities on compliance and technical aspects of the product, on the supply chain, on the structure and actors of the distribution network, on quantities of products on the market, online sales platforms and relevant information for the purpose of ascertaining the ownership of websites.

Under the Regulation, market surveillance authorities are entitled to take measures similar to investigative measures in the future, as they may carry out unannounced on-site inspections, may enter to any premises, land or means of transport that the economic operator in question uses for purposes related to the economic operator's trade, business, craft or profession, in order to identify non-compliance and to obtain evidence. In addition, of course, the obligations known from the previous regulation remain, that is, to require economic operators to take appropriate measures to eliminate non-compliances, to eliminate the risk and to take appropriate measures if the economic operator fails to take appropriate corrective action, or if the non-compliance or risk persists, the right to order the prohibition or restriction of the distribution (marketing) of the product or the withdrawal or recall of the product.

One of the biggest innovations of the Regulation, in addition to redefining the chain of responsibility, is the creation of an effective system of sanctions. The legislator envisages that, in the event of a serious risk, market surveillance authorities would have the right to require the removal of related product content from online interfaces or to oblige the economic operator to explicitly display a warning on its online interfaces.

When such a request is not observed, the relevant authority should have the power to require information society service providers to restrict access to the online interface

4. Where does the future of European market surveillance lead?

In addition to the issues outlined in the study, a number of emerging product types are forcing the expansion of the traditional conceptual framework. More and more consumer goods such as cars, baby monitors, refrigerators and toys that are on the market can connect to the internet (Internet of things). Although these products offer several new services and greater convenience to consumers (even if connection to the internet is not a prerequisite for their operation), research shows that there may be a number of problems with their operation and use. In fact, it can endanger the health and physical integrity of consumers or violate their privacy. At the same time, it should be noted that the general safety of these products is subject to product safety rules, however, there are no compliance standards for new types of risks and hazards.

Algorithm-based decision making (ADM – automated decision making) especially when it is based on Big Data is of particular importance to consumers. ADM processes are the most comprehensive systems that affects consumers, from simpler, rule-based decision-making to a high level of sophisticated machine learning. Nowadays, long-distance cruise control, blind spot/lane/traffic sign detection systems keep the car with minimal intervention on the road and also brake in an emergency instead of the driver. In smart homes, personal assistant programs help with life. But neither the car's sensors nor the assistants are able to work without error yet. The role of algorithm-based decision-making will increase in the future and have an increasing impact on the lives of consumers, raising the issues of information self-determination, sovereign decision-making, including the regulation of the new type of product compliance.

Most of the provisions of the Market Surveillance Regulation will apply from 16 July 2021, so companies distributing products on the EU market that are covered by EU harmonization legislation shall be prepared to apply the rules, including the designation of a responsible representative.

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